CREDITABLE COVERAGE GUIDANCE

I. INTRODUCTION

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) added a new prescription drug program to Medicare. (See Part D of Title XVIII of the Social Security Act (Act), referred to here as "Part D" of Medicare.) Prescription drug coverage under Medicare will be available starting January 1, 2006.

Regulations to implement Medicare prescription drug coverage were published January 28, 2005 (70 Fed. Reg. 4193). This guidance pertains to section 1860D-1 of the Act, and the regulation at 42 CFR §423.56.

Under those provisions, most entities that currently provide prescription drug coverage to Medicare beneficiaries must disclose whether the entity's coverage is "creditable prescription drug coverage" (Disclosure Notice). A disclosure is required whether the entity's coverage is primary or secondary to Medicare. Health plans and other entities that must comply with these provisions are listed in the regulation at 42 CFR §423.56(b) and are also referenced on the creditable coverage homepage at http://www.cms.hhs.gov/medicarereform. However, entities that contract with Medicare directly as a Part D plan or that contract with a Part D plan to provide qualified prescription drug coverage are exempt from the disclosure requirement. Thus, for example, an employer or union that provides prescription drug coverage to retirees through a Part D plan is exempt from the disclosure requirement. See the regulation at 42 CFR §423.56(c).

Disclosure of whether prescription drug coverage is creditable provides Medicare beneficiaries with important information relating to their Medicare Part D enrollment. Beneficiaries who are not covered under creditable prescription drug coverage and who choose not to enroll before the end of their initial enrollment period for Part D likely will pay a higher premium on a permanent basis if they subsequently enroll in Part D.

The regulation at 42 CFR §423.56 establishes certain requirements regarding Disclosure Notices, including rules regarding timing and general content requirements. This guidance provides additional information concerning those rules, including the form and manner of providing Disclosure Notices. It also addresses several principles relating to the determination of creditable coverage. Additional guidance will be issued on modifications that may be required on the creditable coverage disclosure for use after November 15, 2005.

Among the entities to which the disclosure requirements of 42 CFR §423.56 apply are Medigap issuers. However, a separate requirement at section 104(a) of MMA requires Medigap issuers to send a notice, during the period of September 15 through November 14, 2005, to policyholders who have prescription drug coverage. That notice must

disclose whether the prescription drug coverage is creditable, along with other specified information. CMS has consulted with the National Association of Insurance Commissioners in developing a notice of creditable coverage, and a notice of non-creditable coverage, that Medigap issuers must use to satisfy this obligation under section 104(a) of MMA. They are posted on the CMS Website at http://www.cms.hhs.gov/medicarereform/ CCguidances.asp. **Timely use of these notices by Medigap issuers under section 104(a) will satisfy the beneficiary disclosure requirements under 42 CFR §423.56, to the extent those requirements permit or compel disclosure to Medicare beneficiaries by November 14, 2005.**

Please see the CMS Website at http://www.cms.hhs.gov/medicarereform for specific information on how the information contained in this Creditable Coverage Guidance document applies to Medigap issuers.

II. OVERVIEW OF REGULATORY REQUIREMENTS

Who Receives the Disclosure Notice?

The Disclosure Notice must be provided to all Part D eligible individuals who are covered under, or who apply for, the entity's prescription drug coverage. Neither the statute nor the regulations create any exemption based on whether prescription drug coverage is primary or secondary coverage to Medicare Part D. Thus, for example, the Disclosure Notice requirement applies with respect to Medicare beneficiaries who are active employees and those who are retired, as well as Medicare beneficiaries who are covered as spouses under active or retiree coverage.

The entity must also provide a disclosure of creditable coverage status to the Centers for Medicare & Medicaid Services (CMS) on an annual basis, as outlined in the regulation at 42 CFR §423.56(e). CMS will provide future guidance relating to disclosure to CMS.

While the entity that provides the coverage is responsible for providing the notice, nothing in the regulation prevents that entity from arranging to have it provided by a third party.

Part D eligible individuals- An individual is a Part D eligible individual if:

1. The individual is entitled to Medicare Part A and/or enrolled in Part B, as of the effective date of coverage under the Part D plan; and

2. The individual resides in the service area of a prescription drug plan (PDP) or of a Medicare Advantage plan that provides prescription drug coverage (MA-PD). (For purposes of the Part D regulations, an individual who is living abroad or is incarcerated is not eligible for Part D because he or she is not considered to "reside" in the service area of a Part D plan.)

Note that in general, an individual becomes "entitled to" Medicare Part A when the person actually has Part A coverage, and not simply when the person is first eligible. A person has Part A coverage without being subject to monthly premiums if the person has attained age 65 and has monthly social security benefits or is a qualified railroad retirement beneficiary. Individuals under age 65 may also become entitled to Medicare Part A benefits if they receive at least 24 months of social security or railroad retirement benefits based on disability. An individual who is eligible for social security benefits but has not applied for such benefits becomes entitled to Medicare Part A only upon the filing of an application for Part A benefits.

Detailed information about Medicare Part A and Part B eligibility and enrollment is provided in the CMS publication "Enrolling in Medicare" (publication number 11036). This publication is available on line at www.medicare.gov http://www.medicare.gov/publications/pubs/pdf/11036.pdf. Medicare beneficiaries should be directed to their local Social Security (or Railroad Retirement) office for questions about when and how to enroll in Medicare.

Enrollment in Part D - At the beginning of the Part D program, there is an Initial Open Enrollment Period for Part D for all Medicare beneficiaries that begins on November 15, 2005 and extends through May 15, 2006. Subsequently, when an individual's Part B Initial Enrollment Period (IEP) extends beyond May 15, 2006, the Initial Enrollment Period for Part D is concurrent with the individual's IEP for Part B. The IEP for Part B is the 7-month period that begins 3 months before the month an individual first meets the eligibility requirements for Part B and ends 3 months after the month of first eligibility.

If, by the end of an individual's Initial Enrollment Period for Part D, the individual has not enrolled in a Medicare prescription drug plan and does not have creditable prescription drug coverage for any period of 63 days or longer, the individual will likely have to pay a higher premium charge for late enrollment.

As stated in the regulation at 42 CFR §423.56(a)(3)(iii), an individual who becomes entitled to Medicare Part A or enrolled in part B for a retroactive effective date has an initial enrollment beginning with the month in which notification of the Medicare determination is received and ending on the last day of the third month following the month in which the notification was received.

Late Enrollment Penalty (Also referred to as "Higher Premium Charge")

The regulation at 42 CFR §423.46 provides for a late enrollment penalty for Part D eligible individuals who go without any creditable prescription drug coverage for any continuous period of sixty-three (63) days or longer after the end of their initial enrollment period in Part D, and then enroll in Part D. The higher premium charge is based on the number of months that the individual did not have creditable coverage. The premium that would otherwise apply is increased by at least 1% for each month without creditable coverage. While this percentage will apply for as long as the individual

remains enrolled in Part D, the higher premium charge will actually increase each year, because the percentage increase will be applied to each subsequent year's base premium. If Part D eligible individuals are covered under a plan that is providing creditable prescription drug coverage, they will not be assessed a late enrollment penalty if they choose to enroll in Medicare prescription drug coverage at a later date. However, they will be assessed late enrollment penalties if they choose to drop coverage before they can enroll in a Medicare prescription drug plan (or lose coverage and do not promptly take advantage of the resulting Special Enrollment Period), and they go without any creditable coverage for a continuous period of 63 days or longer.

If Part D eligible individuals are covered under a plan that is providing non-creditable prescription drug coverage, they will need to enroll in a Part D plan during the Initial Open Enrollment Period if they do not want to pay a late enrollment penalty. There are limited times in the year in which beneficiaries can enroll (November 15- December 31), and if they do not enroll during the initial open enrollment period, they will likely pay a late enrollment penalty if they choose to join at a later time, unless they had another source of creditable coverage.

DISCLAIMER: The above guidance regarding late enrollment penalties under Medicare is intended to give entities general information regarding the provisions contained in the regulation at 42 CFR §423.46 and §423.286 (c)(3) and in 70 Fed. Reg. 13397, 13399
(Mar. 21, 2005).

Creditable Coverage Definition and Determination

As defined in the regulation at 42 CFR §423.56(a), coverage is creditable if the actuarial value of the coverage equals or exceeds the actuarial value of standard Medicare prescription drug coverage, as demonstrated through the use of generally accepted actuarial principles and in accordance with CMS actuarial guidelines. In general, this actuarial determination measures whether the expected amount of paid claims under the entity's prescription drug coverage is at least as much as the expected amount of paid claims under the standard Medicare prescription drug benefit.

This determination is identical to the first prong of the actuarial equivalence test (gross test) that is applied in the regulation at 42 CFR §423.884 when an employer or union applies for the retiree drug subsidy under that section. It does not take into account whether the coverage is financed by the beneficiary or entity.

For plans that have multiple benefit options, the regulation requires that entities apply the actuarial value test separately for each benefit option. A benefit option is defined in the regulation at 42 CFR §§423.882 as a particular benefit design, category of benefits, or cost-sharing arrangement offered within a group health plan.

III. POLICY GUIDANCE

The following are clarifications and other guidance relating to the above requirements:

Attestation

The determination of creditable coverage status does not require an attestation by a qualified actuary unless the entity is an employer or union electing the retiree drug subsidy. See the regulation at 42 CFR §423.884(d).

Benefit Designs for Simplified Determination of Creditable Coverage Status

If an entity is not an employer or union that is applying for the retiree drug subsidy, it can determine that its prescription drug plan's coverage is creditable if the plan design meets all four of the following standards. However, the standards listed under 4(a) and 4(b) may not be used if the entity's plan has prescription drug benefits that are integrated with benefits other than prescription drug coverage (i.e. Medical, Dental, etc.). Integrated plans must satisfy the standard in 4(c).

A prescription drug plan is deemed to be creditable if it:

1) Provides coverage for brand and generic prescriptions;
2) Provides reasonable access to retail providers and, optionally, for mail order coverage;
3) The plan is designed to pay on average at least 60% of participants' prescription drug expenses; and
4) Satisfies at least one of the following:
   a) The prescription drug coverage has no annual benefit maximum benefit or a maximum annual benefit payable by the plan of at least $25,000, or
   b) The prescription drug coverage has an actuarial expectation that the amount payable by the plan will be at least $2,000 per Medicare eligible individual in 2006.
   c) For entities that have integrated health coverage, the integrated health plan has no more than a $250 deductible per year, has no annual benefit maximum or a maximum annual benefit payable by the plan of at least $25,000 and has no less than a $1,000,000 lifetime combined benefit maximum.

Form, Manner and Content of Creditable Coverage Disclosure from Entity to CMS

The regulation at 42 CFR §423.56(e) requires all entities described in the regulation at 42 CFR §423.56(b) to disclose to CMS whether their prescription drug coverage is creditable or non-creditable. The disclosure must be made to CMS on an annual basis, and upon any change that affects whether the coverage is creditable. CMS will provide the timing, format, and model language for disclosures statements to CMS in further guidance.

Content of Creditable Coverage Disclosures from Entity to Beneficiaries.

CMS has provided sample language that entities can (but are not required to) use when disclosing creditable coverage status to beneficiaries. Links to that language are found at the end of this document. The sample/model language applies to the Initial Open Enrollment Period (IEP) only (November 15, 2005-May 15, 2006). Subsequent sample/model language will be provided in further guidance for new plan enrollees (those with Part D Initial Enrollment Periods after May 15, 2006) and for use in future plan years.

Entities that choose not to use the sample language must provide Disclosure Notices that meet the following content standards.

Content of Creditable Coverage Disclosures from Entity to Beneficiaries – Creditable Coverage.

If the prescription drug coverage offered by the entity is determined to be Creditable Coverage, the disclosure notice to the beneficiary must address the following information elements:

1.) That the entity has determined that the prescription drug coverage it provides is creditable;
2.) The meaning of creditable coverage, i.e., that the amount the plan expects to pay on average for prescription drugs for individuals covered by the plan in 2006 is the same or more than what standard Medicare prescription drug coverage would be expected to pay on average; and
3.) An explanation of why creditable coverage is important and a caution that even though coverage is creditable, the person could be subject to payment of higher Part D premiums if the person subsequently has a break in creditable coverage of 63 days or more before enrolling in a Part D plan.

CMS recommends that the entities also provide the following clarifications in their disclosure statements:

- An explanation of a beneficiary's rights to a notice, i.e., the times when a beneficiary can expect to receive a notice and the times that a beneficiary can request a copy of the notice.

- An explanation of the option(s) that beneficiaries will have available to them when the Medicare Part D benefit becomes available. These options may include, for example:
    - that they can retain their existing coverage and choose not to enroll in a Part D plan; or
    - that they can enroll in a Part D plan as a supplement to, or in lieu of, the other coverage.

- A clarification that if the current prescription drug coverage is integrated with other health coverage (i.e. Medical, Dental, etc.), whether the covered Medicare individuals will still be eligible to receive all of their current health coverage if they choose to enroll in a Medicare prescription drug plan.

- A clarification of the circumstances (if any) under which the individual could get his/her prescription drug coverage back if they drop their current coverage and enroll in Medicare prescription drug coverage.

- Information be provided to the Medicare individual on how to get extra help paying for a Medicare prescription drug plan including the contact information for the Social Security Administration (SSA).

  Recommended CMS language:

  For people with limited income and resources, extra help paying for a Medicare prescription drug plan is available. Information regarding this program is available through the Social Security Administration (SSA). For more information about this extra help, visit SSA online at www.socialsecurity.gov, or call them at 1-800-772-1213 (TTY 1-800-325-0778).

Content of Coverage Disclosures from Entity to Beneficiaries –Non-Creditable Coverage.

If the prescription drug coverage offered by the entity is determined to be Non-Creditable Coverage, the disclosure notice to the beneficiary must address the following information elements in their Non-Creditable Coverage Disclosure Statement:

1.) That the entity has determined that the prescription drug coverage it provides is not creditable;
2.) The meaning of creditable coverage, i.e., that the amount the plan expects to pay on average for prescription drugs for individuals covered by the plan in 2006 is less than what standard Medicare prescription drug coverage would be expected to pay on average;
3.) That an individual may only enroll in a Part D plan from November 15, 2005 through May 15, 2006 and at other specified times thereafter; and
4.) An explanation of why creditable coverage is important and that the individual may be subject to payment of higher Part D premiums if the person fails to enroll in a Part D plan when first eligible.

CMS recommends that the entities also provide the following clarifications in their disclosure statements:

- An explanation of a beneficiary's rights to a notice, i.e., the times when a beneficiary can expect to receive a notice and the times that a beneficiary can request a copy of the notice.

- An explanation of the option(s) that beneficiaries will have available to them when the Medicare Part D benefit becomes available. These options may include, for example:
  - that they can retain their existing coverage and choose not to enroll in a Part D plan; or
  - that they can enroll in a Part D plan as a supplement to, or in lieu of, the other coverage.

- A clarification that if the current prescription drug coverage is integrated with other health coverage (i.e. Medical, Dental, etc.), whether the covered Medicare individuals will still be eligible to receive all of their current health coverage if they choose to enroll in a Medicare prescription drug plan.

- Information be provided to the Medicare individual on how to get extra help paying for a Medicare prescription drug plan including the contact information for the Social Security Administration (SSA).

  Recommended CMS language:

  For people with limited income and resources, extra help paying for a Medicare prescription drug plan is available. Information regarding this program is available through the Social Security Administration (SSA). For more information about this extra help, visit SSA online at www.socialsecurity.gov, or call them at 1-800-772-1213 (TTY 1-800-325-0778).

Form and Manner of Creditable Coverage Disclosure from Entity to Beneficiaries

This guidance clarifies that entities have flexibility in the form and manner of providing Disclosure Notices to beneficiaries. The notice need not be sent as a separate mailing. The Disclosure Notice may be provided with other plan participant information materials (including enrollment and/or renewal materials). The entity may provide a single disclosure notice to the covered Medicare individual and all Medicare eligible dependent(s) covered under the same plan. However, the entity is required to provide a separate disclosure notice if it is known that any spouse or dependent that is Medicare eligible resides at a different address than where the participant/policyholder materials were mailed.

An entity can provide a Disclosure Notice through electronic means only if the Medicare beneficiary has indicated to the entity that s/he has adequate access to electronic information. An entity must not take the right to provide beneficiary material via electronic means as a permissible way to deliver documents to all beneficiaries. Before beneficiaries agree to receive their information via electronic means, they must be

informed of their right to obtain a paper version, how to withdraw their consent, update address information, and identify any hardware or software requirements to access and retain the creditable coverage disclosure.

If the beneficiary consents to an electronic transfer of the notice, a valid e-mail address must be provided to the entity and the consent from the beneficiary must be submitted electronically to the entity. This ensures the beneficiary's ability to access the information as well as ensure that the system for furnishing these documents results in actual receipt. The stand-alone disclosure format must use the sample disclosure notice **or** the required disclosure elements as outlined in this guidance. In addition to having the disclosure notice sent to the beneficiary's email address, the notice must be posted on the entity's website, if applicable, with a link to the creditable coverage disclosure notice on the entity's home page.

If entities choose to incorporate creditable coverage disclosures with other plan participant information, then the disclosures must be prominent and conspicuous. This means that the statements (or a reference to the section in the document being provided to the beneficiary that contains the required statement) must be prominently referenced in at least 14-point font in a separate box, bolded, or offset on the first page that begins the plan participant information being provided.

Example of reference to creditable or non-creditable coverage requirements:

> ***If you have Medicare or will become eligible for Medicare in the next 12 months, a new Federal law gives you more choices about your prescription drug coverage, starting in 2006. Please see page xx for more details.***

Timing of Creditable Coverage Disclosure from Entity to Beneficiaries

The regulation at 42 CFR §423.56(f) specifies the times when creditable coverage disclosures must be made to Part D eligible individuals. At a minimum, disclosure must be made at the following times:

1. Prior to the Medicare Part D Annual Coordinated Election Period (ACEP) – beginning November 15th through December 31st of each year;
2. Prior to an individual's Initial Enrollment Period (IEP) for Part D, as described under 423.38(a);
3. Prior to the effective date of coverage for any Medicare eligible individual that joins the plan;
4. Whenever prescription drug coverage ends or changes so that it is no longer creditable or becomes creditable; and
5. Upon a beneficiary's request.

If the creditable coverage disclosure notice is provided to all plan participants, CMS will consider items 1 and 2 to be met. This guidance clarifies that "prior to" means that the

beneficiary must have been provided the Disclosure Notice within the past twelve months.

Additional Guidance

Additional guidance will be issued on the required disclosure statement from the Entity to CMS and on any modifications to the creditable coverage disclosure content that will be required beyond November 15, 2006. CMS may also release Question and Answers relating to Creditable Coverage issues from time to time on the CMS website under the MMA Questions and Issues Database website which can be found at: http://www.cms.hhs.gov/medicarereform/drugcoveragefaqs.asp.

III CONTACT FOR FURTHER INFORMATION

If you would like further information on creditable coverage, you can contact the CMS Employer Policy and Operations Group at epog@cms.hhs.gov.
You can also visit the CMS website link related to creditable coverage issues at: www.cchomepage.com
For a list of preferred terminology, please visit:
http://www.cms.hhs.gov/partnerships/tools/materials/preferredterms.pdf

IV. LINK TO CREDITABLE AND NON-CREDITABLE COVERAGE DISCLOSURE NOTICES

- **Model Beneficiary Creditable Coverage Disclosure Notice (to be used prior to 11/15/05) http://www.cms.hhs.gov/medicarereform**
- **Model Beneficiary Non-Creditable Coverage Disclosure Notice (to be used prior to 11/15/05) http://www.cms.hhs.gov/medicarereform**